

Attorney Docket No.: UIC0002US
Inventors: Wang, Zaijie
Serial No.: 10/769,536
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REMARKS

Claims 1-27 were pending in this application and have been canceled by this preliminary amendment and replaced by new claims 28-29. No new matter has been added by this amendment. Applicant is respectfully requesting reconsideration of the restriction requirement in view of the following remarks.

The originally filed claims have been subjected to a Restriction Requirement under 35 U.S.C. §121 by the Examiner in this case. The Examiner suggests that restriction of the present invention into the following groups is required:

Group I, claims 1-19, drawn to a method of treating or preventing pain by administering an opiate analgesic and a calcium calmodulin dependent protein kinase (CaMKII) inhibitor, classified in various classes depending upon the inhibitor;

Group II, claims 20-21, drawn to reducing, reversing or preventing tolerance to an opiate analgesic in an individual undergoing opiate analgesic therapy by administering CaMKII inhibitor, classified in various classes depending upon the inhibitor;

Group III, claim 22, drawn to a method of reversing or preventing dependence on an analgesic by administering CaMKII inhibitor, classified in various classes depending upon the inhibitor;

Group IV, claim 23, drawn to a method of treating opiate analgesic withdrawal by administering CaMKII inhibitor, classified in various classes depending upon the inhibitor;

Group V, claims 24-26, drawn to a composition comprising CaMKII inhibitor and an opiate analgesic and an excipient,

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classified in various classes depending upon the structure of the inhibitor;

Group VI, claim 27, drawn to a method of identifying an inhibitor of an CaMKII by administering a candidate compound to a morphine tolerant mammal and monitoring calcium calmodulin kinase expression in the mammal.

The Examiner suggests that Inventions V and I-IV and VI are related as product and process of use; however, are distinct because the processes for using the products can be practiced with materially different products. It is suggested that because the inventions of Groups I-V and VI have a separate status in the art and the search for the compositions and various methods are not coextensive, searching the inventions of Groups I-IV would impose a burden on the Examiner. Applicant is required to elect one of the Groups to be examined.

Further, the Examiner suggests that claims 1-26 are generic to the following disclosed patentably distinct species: 1) specific opiate analgesics and 2) specific calcium calmodulin dependent protein kinase inhibitors. The Examiner has required Applicant to elect a single disclosed species for both the opiate analgesic and the CaMKII inhibitor for any elected Group.

Applicant respectfully disagrees and traverses this restriction requirement and species election.

Applicant has appreciated that CaMKII inhibitors can prevent and reverse the chronic actions of opiate analgesics without modulating the acute actions thereof. Specifically, Applicant has demonstrated that the administration of a CaMKII activity inhibitor such as KN93 prevents and reverses established tolerance and dependence to an opium alkaloid such as morphine

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(see Figures 5-9). Therefore, upon review of the restriction requirement and pending claims, Applicant has appreciated the necessity of clarifying the novel features of the present invention. Accordingly, Applicant is canceling claims 1-27 and presenting new claims 28 and 29 for prosecution. New claim 28 reads on a method for preventing or reversing the chronic actions of an opium alkaloid by administering to an individual undergoing opium alkaloid therapy an effective amount of an inhibitor which inhibits the activity of calcium calmodulin dependent protein kinase II activity. Support for new claim 28 can be found in the specification (see, e.g., page 20, lines 22-29; page 21, lines 18-22; and pages 22-24, sections 1 and 2), claims 20-22 as originally filed, and Figures 5-9, which illustrate the method of new claim 28. New claim 29 reads on a composition comprising an inhibitor which inhibits the activity of calcium calmodulin dependent protein kinase II, an opium alkaloid, and an excipient. Support for new claim 29 is found at pages 22-24 (sections 1 and 2) of the specification and claim 24 as originally filed. In view of these amendments, the subject matter of Groups II and III are now presented in claim 28 and Group V in claim 29.

As claims 28 and 29 are related as product and process of use, a search of the relevant prior art pertaining to a composition comprising an inhibitor which inhibits the activity of calcium calmodulin dependent protein kinase II, an opiate analgesic, and an excipient would reveal art related to methods for using the same to prevent or reverse the chronic actions of an opiate analgesic. Therefore, no additional burden would be incurred by the Examiner in this case by searching and examining together the subject matter of new claims 28 and 29 (Groups II,

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III, and V). Accordingly, reconsideration of this Restriction Requirement is respectfully requested.

Applicant further respectfully disagrees with the required species election. In view of new claims 28 and 29, Applicant has clarified the nature of the CaMKII inhibitor (i.e., an inhibitor which inhibits the activity of CaMKII) and the nature of the opiate analgesic (i.e., an opium alkaloid). In this regard, the disclosure at pages 22-24 teach CaMKII inhibitors of new claims 28 and 29 sharing the common characteristic of inhibiting the activity of CaMKII. This is in contrast to nucleic acid-based inhibitors which inhibit the expression of CaMKII. Moreover, opium alkaloids of new claims 28 and 29 are disclosed at page 21 (lines 18-22) and are related as being structurally derived from morphine. MPEP 808.02 states that "Where, as disclosed in the application, the several inventions claimed are related, and such related inventions are not patentably distinct as claimed, restriction under 35 U.S.C. 121 is never proper (MPEP Section 806.05)." In this regard, the claimed species of an inhibitor which inhibits the activity of CaMKII and an opium alkaloid, as disclosed in the application, possess at least one property in common which is mainly responsible for their function in the claim and therefore would be improperly be restricted under 35 U.S.C. 121. In view of the amendments to the claims and accompanying remarks, reconsideration and withdrawal of the required species election is respectfully requested.

However, in an earnest effort to be completely responsive, Applicants hereby elect to prosecute the subject matter presented in new claim 28, drawn to a method for preventing or reversing the chronic actions of an opiate analgesic using an inhibitor

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which inhibits the activity of calcium calmodulin dependent protein kinase II, with traverse.

Respectfully submitted,



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